

Food and Drug Administration, HHS

§ 522.2670

(b) *Cats.* Treatment of upper respiratory infections when caused by *Staphylococci* spp. and hemolytic *Streptococci* spp. and for feline pneumonitis when caused by tylosin susceptible organisms.

(iii) *Limitations.* For intramuscular use only. If there is no response to therapy in 5 days, diagnosis and treatment should be reassessed. Use a 50-milligram-per-milliliter solution only. Dogs and cats receiving a dose of less than 50 milligrams (1 milliliter) should be dosed with a tuberculin syringe. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 48643, Oct. 2, 1981, as amended at 47 FR 9398, Mar. 5, 1982; 50 FR 49841, Dec. 5, 1985; 50 FR 50292, Dec. 10, 1985; 53 FR 40728, Oct. 18, 1988; 59 FR 14365, Mar. 28, 1994; 62 FR 35077, June 30, 1997]

§ 522.2662 Xylazine hydrochloride injection.

(a) *Specifications.* Xylazine hydrochloride injection is a sterile aqueous solution containing xylazine hydrochloride equivalent to 100 milligrams of xylazine in each milliliter of solution when intended for use in horses, wild deer, and elk, and 20 milligrams of xylazine per milliliter of solution when intended for use in dogs and cats.

(b) *Sponsor.* See 000856 in § 510.600(c) of this chapter for use in horses, wild deer, and elk. See 000859 and 061651 in § 510.600(c) of this chapter for use in horses, wild deer, elk, dogs, and cats. See 061690 in § 510.600(c) of this chapter for use in horses, wild deer, elk, dogs, and cats. See 000010 in § 510.600(c) of this chapter for use in horses only.

(c) *Conditions of use.* (1) The drug is used in horses, wild deer, elk, dogs, and cats to produce sedation, as an analgesic, and a preanesthetic to local anesthesia. It may also be used in horses, dogs, and cats as a preanesthetic to general anesthesia.

(2) It is administered as follows:

(i) To horses from a solution containing 100 milligrams of xylazine per milliliter, intravenously at 0.5 milligram per pound of body weight, or intramuscularly at 1.0 milligram per pound of body weight.

(ii) To dogs and cats from a solution containing 20 milligrams of xylazine

per milliliter; intravenously at 0.5 milligram per pound of body weight or intramuscularly or subcutaneously at 1.0 milligram per pound of body weight. In dogs over 50 pounds, a dosage of 0.5 mg. per pound administered intramuscularly may provide sufficient sedation and/or analgesia for most procedures.

(iii) To wild deer and elk from a solution containing 100 milligrams of xylazine (as xylazine hydrochloride) per milliliter, intramuscularly, by hand syringe or syringe dart, in the heavy muscles of the croup or shoulder as follows:

(a) Fallow deer, 2 to 4 milligrams per pound.

(b) Mule deer, sika deer, and whitewater, 1 to 2 milligrams per pound.

(c) Elk, 0.25 to 0.5 milligram per pound.

(3) Not to be administered to food-producing animals.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 41 FR 24884, June 21, 1976; 41 FR 28265, July 9, 1976; 53 FR 4848, Feb. 18, 1988; 53 FR 23608, June 23, 1988; 53 FR 40728, Oct. 18, 1988; 55 FR 18724, May 4, 1990; 55 FR 32616, Aug. 10, 1990; 59 FR 14367, Mar. 28, 1994; 60 FR 33110, June 27, 1995; 60 FR 35122 and 35123, July 6, 1995; 61 FR 46548, Sept. 4, 1996; 62 FR 35077, June 30, 1997]

§ 522.2670 Yohimbine injectable.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains either 2 or 5 milligrams of yohimbine (as hydrochloride).

(b) *Sponsor.* See 061690 in § 510.600(c) of this chapter for use of 2 milligrams per milliliter solution in dogs.

(1) *Amount.* 0.05 milligram per pound (0.11 milligram per kilogram) of body weight.

(2) *Indications for use.* To reverse the effects of xylazine in dogs.

(3) *Limitations.* For intravenous use in dogs only. Not for use in food-producing animals. Safety of use in pregnant dogs or in dogs intended for breeding has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) *Sponsor.* See 053923 in § 510.600(c) of this chapter for use of 5 milligrams per milliliter solution in deer and elk.

§ 522.2680

(1) *Amount.* 0.2 to 0.3 milligram per kilogram of body weight.

(2) *Indications for use.* As an antagonist to xylazine sedation in free ranging or confined members of the family Cervidae (deer and elk).

(3) *Limitations.* For intravenous use only. Do not use in domestic food-producing animals. Do not use for 30 days before or during hunting season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 8543, Feb. 16, 1993, as amended at 60 FR 57832, Nov. 22, 1995]

§ 522.2680 Zeranor.

(a) *Specifications.* Each pellet contains 12, 18, or 20 milligrams (mg) zeranol.

(b) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.760 of this chapter.

(d) *Conditions of use*—(1) *Beef cattle*—(i) *Amount.* 36 mg zeranol (one implant consisting of 3 pellets, each pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use*—(A) For increased rate of weight gain and improved feed conversion in weaned beef calves, growing beef cattle, feedlot steers, and feedlot heifers.

(B) For increased rate of weight gain in suckling calves.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in bulls intended for reproduction or in dairy animals. Do not use before 1 month of age or after weaning in heifers intended for reproduction.

(2) *Feedlot lambs*—(i) *Amount.* 12 mg zeranol (one implant consisting of 1 pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed conversion.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in breeding animals. Do not implant animals within 40 days of slaughter.

(3) *Steers fed in confinement for slaughter*—(i) *Amount.* 72 mg zeranol (one implant consisting of 6 pellets, each pellet containing 12 mg zeranol) per implant dose.

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(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only.

(4) *Pasture cattle (slaughter, stocker, feeder steers, and heifers)*—(i) *Amount.* 138 mg zeranol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg zeranol and a seventh pellet containing 18 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* Implant subcutaneously in ear only.

[59 FR 19639, Apr. 25, 1994; 60 FR 26360, May 17, 1995, as amended at 62 FR 61625, Nov. 19, 1997; 64 FR 46840, Aug. 27, 1999; 67 FR 6867, Feb. 14, 2002]

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

Sec.

524.86 Amitraz liquid.

524.154 Bacitracin or bacitracin zinc-neomycin sulfate-polymyxin B sulfate ophthalmic ointment.

524.155 Bacitracin zinc-polymyxin B sulfate-neomycin sulfate-hydrocortisone or hydrocortisone acetate ophthalmic ointment.

524.390 Chloramphenicol ophthalmic and topical dosage forms.

524.390a Chloramphenicol ophthalmic ointment.

524.390b Chloramphenicol ophthalmic solution.

524.390d Chloramphenicol-prednisolone ophthalmic ointment.

524.402 Chlorhexidine ointment.

524.450 Clotrimazole cream.

524.463 Copper naphthenate solution.

524.520 Cuprimyxin cream.

524.575 Cyclosporine ophthalmic ointment.

524.660 Dimethyl sulfoxide ophthalmic and topical dosage forms.

524.660a Dimethyl sulfoxide solution.

524.660b Dimethyl sulfoxide gel.

524.770 Doramectin.

524.802 Enrofloxacin, silver sulfadiazine emulsion.

524.814 Eprinomectin.

524.900 Famphur.

524.920 Fenthion.

524.960 Flumethasone, neomycin sulfate, and polymyxin B sulfate ophthalmic solutions.

524.981 Fluocinolone acetonide ophthalmic and topical dosage forms.

524.981a Fluocinolone acetonide cream.